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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,368	08/06/2003	Kenneth Stewart	6714-46501	6917
23646 7590 10/07/2010 BARNES & THORNBURG LLP 750-17TH STREET NW SUITE 900 WASHINGTON, DC 20006-4675			EXAMINER NELSON, CHRISTINE L	
			ART UNIT 3775	PAPER NUMBER
			NOTIFICATION DATE 10/07/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/634,368	Applicant(s) STEWART, KENNETH	
	Examiner CHRISTINE L. NELSON	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-45 is/are pending in the application.
- 4a) Of the above claim(s) 35 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,29-31,36 and 38-45 is/are rejected.
- 7) ☒ Claim(s) 24-28 and 32-34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the amendment to the Claims submitted on June 1, 2010.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The trademarks "GoreTex" and "Dacron" are used in the claims. According to MPEP 2173.05, "a trade name does not identify or describe the goods associated with the trademark or trade name." Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 29 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The wording of Claim 29 positively recites the body in the phrase "encapsulates substantially all of the bone instrumentation which

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projects from the bone." Suggested language would include "wherein the hollow cap is *adapted to* encapsulate substantially all of the bone instrumentation which projects from the bone."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 29-30, 36, and 38-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Jennings, Jr. et al. (US patent 6,810,880 B1). Jennings Jr. et al. discloses a hollow cap (Figure 5, 108) and a fastener portion (112). With regard to functional language it is noted that the cover and fastener of Jennings, Jr. et al., appropriately sized and shaped would be fully capable of performing the functions of creating a medically safe barrier that is impermeable and that would protect the bone instrumentation from tissue growth. Further, the fastener portion would be fully capable of securing the cap around bone instrumentation. The hollow cap of Jennings, Jr. et al. would be capable of encapsulating all of the bone instrumentation that projects from the bone, as it can be made of a flexible material (column 6, lines 34-46). The hollow cap of

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Jennings, Jr. et al. can be capable of being permanently anchored (Column 7, lines 23-27) during surgery.

Jennings, Jr. et al. discloses that the bone instrumentation cover device is made of a medically safe material (Column 6, lines 34-46). Further, Jennings, Jr. et al. discloses the combination of a barrier material (Figure 5, 108 and 106) and a bone implant (Column 5, 64-66).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jennings, Jr. et al. in view of Ellman (US Patent Number 4,428,375). Jennings, Jr. et al. discloses the invention substantially as claimed, but does not disclose sutures that are absorbable in vivo for securing the hollow cap. Ellman teaches a fastener portion such as adjustable, multiple sutures (21/22) connected to the lower portion of the cap, and wherein the sutures (21/22) may also be considered non-adjustable (or may be cut) that function to tighten the lower end of the cap onto a fastener. Ellman further discloses that the cap has solid parts (16). The sutures or strings may also be resorbable (Col. 2, lines 30-45). It would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize the sutures of Ellman with the invention of Jennings, Jr. et

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al. as an alternative method of fastening should the patient be unable to tolerate the adhesive as taught by Jennings, Jr. et al.

Claims 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jennings, Jr. et al. in view of Barron. Jennings, Jr. et al discloses the claimed invention except for wherein the hollow cap comprises a hydrogel. Barron discloses that a hydrogel (see Claim 5) may be used to protect and surround bone implants or instrumentation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Jennings, Jr. et al having at least a hollow cap comprising a hydrogel in view of Barron so that the barrier can better protect the instrumentation by being biocompatible as well as absorbing body fluid in the surgical area.

Allowable Subject Matter

Claims 24-28 and 32-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to claims 23, 29-31, 36, and 38-45 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE L. NELSON whose telephone number is (571)270-5368. The examiner can normally be reached on Monday through Friday 7:30 to 5:00 - first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTINE L. NELSON/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775

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